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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,263	05/31/2000	Chicheng Wang	1225.003US1	2811

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EXAMINER
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WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

22

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/583,263

Applicant(s)

WANG, CHICHENG

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 and 23 is/are allowed.
- 6) ☒ Claim(s) 1,8-12 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 2-7, 13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 8, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al. (5,925,075). Myers et al. disclose, in figure 6 and in col. 7, lines 19-30, a stent and a system for retaining a polymeric, PTFE film or sheet or expandable sleeve (20), where the stent includes a structural support comprising a patterned surface (e.g., with apertures) and a first unexpanded configuration and a second expanded configuration, and where the film is retained by the structural support entirely by friction (and without adhesive or chemical bonding) and is wrapped around the structural support such that first and second layers are formed (e.g., 45).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. in view of Tartaglia et al. (5,637,113). Myers et al. disclose the invention substantially as claimed, but do not disclose a polymeric film with one or more drugs or apertures. Tartaglia et al. teach, in col. 4, lines 25 to 46, a polymeric film loaded with drugs and having apertures. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Tartaglia et al., to load drugs and define apertures in the polymeric film of Myers et al. Such modifications would allow, for example, the loading of a drug that is anti-thrombogenic, while apertures can promote endothelialization when the stent is deployed in vasculature.
5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (4,441,215) in view of Myers et al. Kaster discloses the invention substantially as claimed. Kaster discloses, in col. 6, line 25 to col. 7, line 44, a method for adhering a polymeric sheet (32) to a stent structural member (10) having a raised, textured design (a herringbone braid). However, Kaster does not disclose wrapping the sheet around the structural member such that a first layer and an overlapping second layer are formed. Myers et al. teach wrapping a polymeric sheet around a structural member

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such that a first layer and an overlapping second layer are formed. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Myers et al., to modify the method of Kaster, so that a polymeric sheet is wrapped around the structural member such that a first layer and an overlapping second layer are formed. Such a modification provides a convenient and effective means for affixing a polymeric film to a structural member.

6. Claims 16, 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. in view of Pinchuk (5,053,048). Myers et al. disclose the invention substantially as claimed. However, Myers et al. do not disclose an expandable structural member with an outer surface that is roughened or textured. Pinchuk teaches, in col. 3, lines 1-22, structural members with roughened or textured surfaces. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Pinchuk, to roughen or texturize the outer surface of the structural member of Myers et al. Such a modification would improve of adhesion of the polymeric sheet or sleeve to the structural member.

7. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. in view of Pinchuk as applied to claims 16 and 19 above, and further in view of Tartaglia et al. Myers et al. in view of Pinchuk disclose the invention substantially as claimed, but do not disclose a polymeric sleeve or sheet containing drugs. Tartaglia et al. teach, in col. 4, lines 25 to 46, a polymeric sleeve or sheet loaded with drugs. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Tartaglia et al., to load drugs in the polymeric sleeve

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or sheet of Myers et al. Such a modification would allow, for example, the loading of a drug that is anti-thrombogenic onto the stent assembly and thus improve the stenting performance in vasculature.

***Allowable Subject Matter***

8. Claim 22 and 23 are allowed.

9. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination discloses, inter alia, a structural support of a stent having an outer surface with a pattern of raised squares. Also, the prior art of record does not disclose a stent and a polymeric film or sheet or tube wrapped around the stent such that a first layer and an overlapping second layer are formed, where the stent comprises an outer surface having at least one or more of raised triangles, spikes, and raised squares.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10. Claims 2-7, 13, and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a stent and a

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polymeric film or sheet or tube wrapped around the stent such that a first layer and an overlapping second layer are formed, where the stent comprises an outer surface having raised triangles, spikes, and/or raised squares.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

### ***Response to Amendment***

12. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Palmaz (4,776,337) and Lewis et al. (5,718,973) teach stents with wrapped structural supports.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.

A handwritten signature in black ink that reads "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo  
Primary Examiner

March 10, 2004